



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 28, 2014

Hartalega Sdn. Bhd.
Ms. Nurul Aisyah Kong
Senior Manager – Quality Assurance
No. 7, Kawasan Perusahaan Suria
45600 Bestari Jaya
Selangor Darul Ehsan, Malaysia

Re: K133956

Trade/Device Name: Nitrile Powder Free Examination Glove with Colloidal Oatmeal Skin
Protectant - White (Lavender Scent);
Nitrile Powder Free Examination Glove with Colloidal Oatmeal Skin
Protectant - Dawn Blue (Lavender Scent) and
Nitrile Powder Free Examination Glove with Colloidal Oatmeal Skin
Protectant - Lemon Green (Lavender Scent)

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination glove

Regulatory Class: I

Product Code: LZA

Dated: April 25, 2014

Received: April 28, 2014

Dear Ms. Kong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

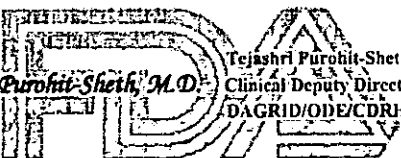
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tejashtree Purohit-Sheth, M.D.
Clinical Deputy Director
DAGR1D/ODE/CDRH FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1.0

INDICATION FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K133956

Device Name

Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - White (Lavender Scent)

Indications for Use (Describe)

The Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - White (Lavender Scent) is a non - sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Sreekanth
Gutala -S**

Digitally signed by Sreekanth Gutala -S
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ou=FDA, cn=People,
c=US, email=Sreekanth.Gutala-S@FDA.HHS.gov,
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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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Indications for Use

510(k) Number (if known)
K133956

Device Name

Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - Dawn Blue (Lavender Scent)

Indications for Use (Describe)

The Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - Dawn Blue (Lavender Scent) is a non - sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Sreekanth
Gutala -S

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Indications for Use

510(k) Number (if known)
K133956

Device Name

Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - Lemon Green (Lavender Scent)

Indications for Use (Describe)

The Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant - Lemon Green (Lavender Scent) is a non - sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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